State of Wisconsin
2015 - 2016 LEGISLATURE

LRBs0389/1
TJD&SWB:kjf/amn/wlj

ASSEMBLY SUBSTITUTE AMENDMENT 1,

TO ASSEMBLY BILL 791

February 18, 2016 – Offered by Representative ROHRKASTE.

AN ACT ***to renumber*** 50.08 (3) (h); ***to amend*** 50.08 (2) and 50.08 (3) (a); and ***to create*** 50.08 (3) (bg), 50.08 (3) (bh), 50.08 (3) (fr) and 50.08 (3) (h) 2. of the statutes; **relating to:** informed consent for psychotropic medications in community–based residential facilities.

Analysis by the Legislative Reference Bureau

This substitute amendment requires a community–based residential facility to provide to a resident or e–mail or mail to a person acting on behalf of a resident an informational form for administration of psychotropic medications to the same individuals and under similar circumstances as a nursing home is required to obtain informed consent for administration of psychotropic medications under current law. Current law requires that a nursing home obtain written informed consent before administering a psychotropic medication that contains a boxed warning to any resident who has degenerative brain disorder with exceptions for emergency situations. A psychotropic medication is an antipsychotic, an antidepressant, lithium carbonate, or a tranquilizer. A boxed warning is a warning, described in federal regulations, the text of which is contained in a black outlined box on the drug's label and in the full prescribing information.

Instead of written informed consent, the substitute amendment requires that when first administering a psychotropic medication that has a boxed warning to a

resident who has a degenerative brain disorder, a community–based residential facility shall provide to a resident or, if the resident is incapacitated, e–mail or mail to a person acting on behalf of the resident an informational form. A community–based residential facility may administer the psychotropic medication before the resident or person acting on behalf of the resident has the informational form, but the community–based residential facility must provide the form to the resident or e–mail or mail the form to the person acting on behalf of the resident within 72 hours of first administering the psychotropic medication. The substitute amendment requires that the informational form contains a notification that the resident has been prescribed a medication that has a boxed warning and information from the federal Food and Drug Administration for the specific psychotropic medication the resident has been prescribed. The informational form also notifies the resident, or person acting on behalf of the resident, that if he or she seeks more information that he or she should contact the prescriber of the medication. The community–based residential facility is required to include contact information for the prescriber on the informational form.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 50.08 (2) of the statutes is amended to read:

50.08 **(2)** A physician, an advanced practice nurse prescriber certified under s. 441.16 (2), or a physician assistant licensed under ch. 448, who prescribes a psychotropic medication to a nursing home or community–based residential facility resident who has degenerative brain disorder shall notify the nursing home or community–based residential facility if the prescribed medication has a boxed warning under 21 CFR 201.57.

SECTION 2. 50.08 (3) (a) of the statutes is amended to read:

50.08 **(3)** (a) Except as provided in sub. (3m) or (4), before administering a psychotropic medication that has a boxed warning under 21 CFR 201.57 to a resident of a nursing home who has degenerative brain disorder, a nursing home shall obtain written informed consent from the resident or, if the resident is incapacitated, a

person acting on behalf of the resident, on a form provided by the department under par. (b) or on a form that contains the same information as the form under par. (b).

SECTION 3. 50.08 (3) (bg) of the statutes is created to read:

50.08 **(3)** (bg) When first administering a psychotropic medication that has a boxed warning under 21 CFR 201.57 to a resident of a community–based residential facility who has a degenerative brain disorder, a community–based residential facility shall provide to a resident or, if the resident is incapacitated, send by electronic mail to a person acting on behalf of the resident an informational form described under par. (bh). If the community–based residential facility does not have the electronic mail address of the person acting on behalf of the resident, the community–based residential facility shall send by mail a copy of the informational form to the person acting on behalf of the resident. A community–based residential facility may administer the psychotropic medication before the resident or person acting on behalf of the resident has the informational form, but the community–based residential facility shall provide the informational form to the resident or send by electronic mail or mail the informational form to the person acting on behalf of the resident within 72 hours of first administering the psychotropic medication.

SECTION 4. 50.08 (3) (bh) of the statutes is created to read:

50.08 **(3)** (bh) 1. The department shall make available on its Internet site or, upon request, by mail informational forms for obtaining a signature acknowledging receipt of all of the following:

a. A notification, created by the department, indicating that the resident has been prescribed a medication that has a boxed warning under 21 CFR 201.57.

b. Information created by the federal food and drug administration for the specific psychotropic medication the resident has been prescribed. The community–based residential facility shall obtain the information sheet from the federal food and drug administration or obtain information from the federal food and drug administration's Internet site.

2. The informational form under this paragraph shall contain a notification that if the resident, or person acting on behalf of the resident, if applicable, seeks more information the resident or person acting on behalf of the resident should contact the individual who prescribed the medication. The community–based residential facility shall indicate on the informational form contact information for the prescriber of the medication.

SECTION 5. 50.08 (3) (fr) of the statutes is created to read:

50.08 **(3)** (fr) The community–based residential facility shall maintain a record or maintain proof of providing or sending by electronic mail or mail an informational form under par. (bg) for 15 months from the date the informational form is provided, sent by electronic mail, or mailed.

SECTION 6. 50.08 (3) (h) of the statutes is renumbered 50.08 (3) (h) 1.

SECTION 7. 50.08 (3) (h) 2. of the statutes is created to read:

50.08 **(3)** (h) 2. The community–based residential facility shall use the most current information available from the federal food and drug administration under par. (bh) 1. b.

(END)